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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,105	06/20/2003	J. Fernando Bazan	DX0903K1B	7017

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DNAX RESEARCH, INC.
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EXAMINER	
JALLA, SANJOO	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,105	BAZAN ET AL.	
	Examiner	Art Unit	
	Sanjoo Shree Jalla	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response filed 2/03/06 is acknowledged. Claims 21-40 are pending in the application.

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

   Applicant has amended the Title to "Binding Compounds to IL-B50; Related Reagents and Methods".

   Examiner's position is that the title "binding compound to IL-B50" is considered a new matter and a new title is required that is clearly indicative of the invention to which the claims are directed.

   The amendment filed 2/03/06 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

   The amendment filed on 2/03/06 to the Title "Binding Compounds to IL-B50; Related Reagents and Methods" represents a departure from the specification and the claims as originally filed. Applicant does not point out to specification for support for such compounds. The title is drawn to any compound binding to IL-B50, however the specification on page 7, line 22 discloses a compound having an antibody-binding site that specifically binds to IL-B50.

   Applicant is required to cancel the new matter in the response to this Office action.

3. Applicant's information disclosure, filed 7/21/03 is acknowledged. References AE and AH were not found and have been lined through and have not been considered.

   Applicant's remarks regarding IDS filed on 2/03/06 have been fully considered.

   Applicant's position is that a copy of reference AH, from The Cytokine Handbook, 3rd edition is submitted. Applicants are in the process of locating a copy of reference AE (Friend, Sherree Lee, et al., Experimental Hematology, A thymic stromal cell line supports in vitro development of surface IgM B cells and produces a novel growth factor affecting B and T lineage cells" (1994), pp. 321-328, Vol. 3) and will submit the same when it is available.

   Examiner's position with respect to the IDS filed 7/21/03, is that the Reference AH has been considered and entered on form PTO-892.

4. In view of the amendments filed on 2/3/06, only the following rejections remain.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21 and 28-40 stand rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.
An isolated binding compound that specifically binds a polypeptide consisting of SEQ ID NO: 2 as in claim 21.

The specification and the claims as originally filed do not provide support for the invention as now claimed

Applicant's arguments regarding rejection under first paragraph of 35 U.S.C. 112: filed on 2/03/06 have been fully considered but has not been found to be persuasive.

Applicant's position is that in addition to the original claims, support for this claim can be found, for example, at page 7, lines 20-22 and page 6, lines 22-25. The Office Action states that the claimed invention is much broader than the original claim, which is limited to a binding site of an antibody and not the entire binding compound. Applicants wish to point out that the original claims are directed to binding compounds but not binding sites (see, for example, original claims 11 and 12).

Examiner's position is that the invention claimed is much broader than the original claim which is limited to a binding site of an antibody and not the entire binding compound, and further which specifically binds to at least 17 contiguous amino acids from SEQ ID NO: 2 or 4 and not as claimed in new claim 21 where it specifically binds to SEQ ID NO: 2 and not a portion of it.

6. The instant application claims the benefit of priority to the provisional application Serial No. 60/101,318, filed 09/21/1998. Applicant is advised that because the specific, substantial and credible utility of the instant polypeptide consisting SEQ ID NO: 2 is only disclosed in the specification of continuation application 09/963,347 filed on 09/25/2001, the effective filing date for the instant invention is determined as the filing date of continuation application 09/963,347 i.e. 09/25/2001.

Applicant's arguments regarding priority filed on 2/03/06 have been fully considered.

Applicant's position is that at least one specific, substantial and credible utility has been disclosed in the '318 application. For example, the '318 application discloses that IL-B50 has stimulatory or inhibitory effects on hematopoietic cells, including, e.g., lymphoid cells, such as T-cells, B-cells, natural killer (NK) cells, macrophages, dendritic cells, and hematopoietic progenitors (page 9, lines 9-13 of the '318 application). The '318 application further discloses that IL-B50 is a short chain cytokine exhibiting sequence similarity to IL-7 (page 12, lines 1-4), that IL-B50 and IL-7 are likely to share similar biological functions (page 12, second paragraph, particularly line 32), and that IL-7

exhibits strong effects on lymphopoietic development and differentiation (page 59, lines 21-22). IL-B50 can be used to isolate its receptor (page 49, lines 5-6 of the '318 application), and it was predicted that IL-B50 would bind to the alpha subunit of the IL-7 receptor along with another subunit (page 49, lines 25-28 of the '318 application). Therefore, a skilled artisan would have understood from the '318 application that IL-B50 has similar functions as 1L-7, such as stimulating lymphopoietic development and differentiation, and that IL-B50 and 1L-7 are so closely related that their receptors would share a common subunit. These are real-world, specific utilities. The utilities of binding compounds are also disclosed (see, e.g., pages 26-28 of the '318 application).

Examiner's position is that irrespective of the utility, the "binding compound that specifically binds a polypeptide consisting of SEQ ID No. 2 or SEQ ID No. 4" in claim 21, "SEQ ID No. 4" in claim 21, "K_D of 10 μM or less" in claim 28 and "conjugated to an immunogenic protein" in claim 35, do not find support in the provisional application 60/101,318, filed 09/21/1998. Therefore, the effective filing date for the instant invention is determined as the filing date of continuation application 09/963,347 i.e. 09/25/2001.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that forms the basis for the rejection under this section made in this office action:

A person shall be entitled to a patent unless-

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21-23, 26-28 and 31-35 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,555,520.

The '520 Patent teaches a protein called thymic stromal lymphopoietin (TSLP) that has 91.9% identity with amino acid sequence of SEQ ID NO: 2 of instant application (see a copy of printout of the sequence alignment attached to the office action). Further, '520 Patent teaches monoclonal antibodies that bind TSLP (see page 51, Example 5, Left column).

Further, antibody of '520 Patent that binds TSLP protein will bind polypeptide consisting of SEQ ID NO: 2, as it is an inherent property of an antibody to bind to a protein that has 91.9% homology to the protein it binds to. Further, resulting antibody would be expected to bind the polypeptide with a K_D of 10μM or less.

The reference clearly anticipates the invention.

Applicant's arguments regarding rejection under 35U.S.C. 102(e) filed on 2/03/06 have been fully considered but they are not persuasive.

Applicant's position is that the present claims are entitled to the benefit of the filing date of the '318 application, filed September 21, 1998. Since the '520 patent was filed on May 9, 2001, with an earliest possible priority date of November 13, 1998, it is not prior art with respect to the claimed invention.

Examiner's position as discussed previously is that the effective filing date for the instant invention is determined as the filing date of continuation application 09/963,347 i.e. 09/25/2001, therefore the rejection made by the examiner using '520 Patent filed on May 9, 2001, with an earliest possible priority date of November 13, 1998 stands.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

Claims 24, 25, 29 and 30, stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,555,520 in view of Gavilondo et. al. (BioTechniques, 2000; 29: 128-145).

U.S. Patent No. 6,555,520 has been discussed previously.

U.S. Patent No. 6,555,520 does not teach the antibody to be either chimeric or humanized or single chain Fv or a Fab fragment.

Gavilondo et. al. teaches that it was well known in the art at the time the invention was made to prepare antibody fragments (Fv, Fab or $F(ab)_2$) (see page 133, left hand column, second paragraph), chimeric antibodies, humanized antibodies or single chain antibodies as these are useful for a number of procedures including purification (e.g. affinity chromatography). Further, Gavilondo et. al. teaches the usefulness of monoclonal antibodies and the antibody fragments for therapeutic purposes. In addition, Gavilondo et.al. teaches that antibodies can be produced as genetic fusion proteins with enzymes and other functional groups (i.e. detectable labels) (see page 132, right hand column, 3rd paragraph).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to apply the teachings of Gavilondo et. al. to make a chimeric or humanized or single chain Fv or a Fab fragment antibody that would bind the TSLP protein of the '520 Patent.

One of ordinary skill in the art at the time the invention was made would have been motivated to make antibodies (chimeric or humanized or single chain or a Fab fragment antibody) to TSLP protein that would bind SEQ ID NO: 2 because as taught by Gavilaondo et. al., chimeric, humanized and antibody fragments are useful for a number of procedures including purification (e.g. affinity chromatography) and detection assays as well as diagnostic and therapeutic regimens

because of their smaller size and potentially better tissue penetration and clearance (see page 132, left column-second paragraph, lines 7-12).

From combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Applicant's arguments regarding rejection under 35U.S.C. 103(a) filed on 2/03/06 have been fully considered but they are not persuasive.

Applicant's position is that the present claims are entitled to the benefit of the filing date of the '318 application, filed September 21, 1998. Since the '520 patent was filed on May 9, 2001, with an earliest possible priority date of November 13, 1998, it is not prior art with respect to the claimed invention.

Examiner's position as discussed previously is that the effective filing date for the instant invention is determined as the filing date of continuation application 09/963,347 i.e. 09/25/2001, therefore the rejection made by the examiner using '520 Patent filed on May 9, 2001, with an earliest possible priority date of November 13, 1998 stands.

9. Claims 36-38, stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,555,520 in view of U.S. Patent No: 4,281,061.

U.S. Patent No. 6,555,520 has been discussed previously.

U.S. Patent No. 6,555,520 does not teach a detection kit comprising the binding compound and instruction material and a compartment for storage of the binding compound.

The '061 Patent teaches that reagents for an immunoassay can be provided as kits as a matter of convenience and to optimize the sensitivity of the assay in the range of interest (column 22, line 62 to column 23, line 4).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to include an antibody that binds TSLP protein (and, therefore binds protein of SEQ ID NO: 2) as taught by the '520 Patent, in a kit format for the convenience and economy of the user as taught by the '061 Patent. One would have been motivated to assemble the reagents in a kit format to standardize the reagents for optimization convenience.

From combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Applicant's arguments regarding rejection under 35U.S.C. 103(a) filed on 2/03/06 have been fully considered but they are not persuasive.

Applicant's position is that the present claims are entitled to the benefit of the filing date of the

'318 application, filed September 21, 1998. Since the '520 patent was filed on May 9, 2001, with an earliest possible priority date of November 13, 1998, it is not prior art with respect to the claimed invention.

Examiner's position as discussed previously is that the effective filing date for the instant invention is determined as the filing date of continuation application 09/963,347 i.e. 09/25/2001, therefore the rejection made by the examiner using '520 Patent filed on May 9, 2001, with an earliest possible priority date of November 13, 1998 stands.

10. *Claims 39-40, are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,555,520 in view of U.S. Patent No: 4,281,061 as applied to claims 36-38 above, and in further view of U.S. Patent No: 5,627,043 issued May 6, 1997.*

U.S. Patent No. 6,555,520, and U.S. Patent No: 4,281,061 have been discussed previously.

U.S. Patent No. 6,555,520, and U.S. Patent No: 4,281,061 do not teach a detection kit wherein the detection is performed by using ELISA and for separating bound binding compounds from free binding compounds.

The '043 Patent teaches that the kit can contain a primary antibody that selectively binds to cleaved product, which can be used in, for example, an enzyme immunoassay (for eg. ELISA) or immunoprecipitation assay. (see Detailed Description Text (51)).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to include necessary reagents to perform an enzyme immunoassay or immunoprecipitation assay as taught by the '043 Patent, for the detection of TSLP protein (and, therefore protein of SEQ ID NO: 2) as taught by the '520 Patent, in a kit format for the convenience and economy of the user as taught by the '061 Patent. One would have been motivated to assemble the reagents in a kit format to standardize the reagents for optimization and convenience.

From combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Applicant's arguments regarding rejection under 35U.S.C. 103(a) filed on 2/03/06 have been fully considered but they are not persuasive.

Applicant's position is that the present claims are entitled to the benefit of the filing date of the '318 application, filed September 21, 1998. Since the '520 patent was filed on May 9, 2001, with an earliest possible priority date of November 13, 1998, it is not prior art with respect to the claimed invention.

Examiner's position as discussed previously is that the effective filing date for the instant invention is determined as the filing date of continuation application 09/963,347 i.e. 09/25/2001, therefore the rejection made by the examiner using '520 Patent filed on May 9, 2001, with an earliest possible priority date of November 13, 1998 stands.

11. No claims are allowable.

12. **THIS ACTION IS MADE FINAL**. See MPEP 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1 .136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within 1W0 MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sanjoo Jalla whose telephone number is (571) 272-4453. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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